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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,683

09/29/2005

Tadashi Saito

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EXAMINER

RAMDHANIE, BOBBY

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,683	Applicant(s) SAITO ET AL.	
	Examiner BOBBY RAMDHANIE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,11,12 and 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-10 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :03/18/2008,12/04/2007,07/17/2007,12/08/2006,08/15/2006,09/29/2005.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II; Claims 1-4, 7-10, & 13 in the reply filed on 01/12/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The abstract of the disclosure is objected to because it is unclear how Applicants define the difference between quantitative and semi-quantitative analysis. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4, 7-10, & 13 are rejected under 35 U.S.C. 112, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner how the use limitation of the flow analysis or flow injection analysis system, further limits the structure of the system. The Examiner interprets the capabilities of quantitatively or semi-quantitatively determining elements as an intended

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use. The Examiner also interprets that the sealed vessel with the reagent solution and the limitations of the dependent claims are toward a separate item that is not part of the system.

5. Claims 1-4, 7-10, & 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner if the claim is to a flow analysis system or a flow injection analysis system. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claims 1-4, 7-10, & 13 recites the broad recitations of "a flow analysis system" and "quantitatively," and the claim also recites "a flow injection analysis system" and "semi-quantitatively" which narrow the statement of the range/limitations.

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6. Claims 1-4, 7-10, & 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "semi-quantitatively" in claims 1-4, 7-10, & 13 is a relative term which renders the claims indefinite. The term "semi-quantitatively" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. Claims 1 & 7 recite the limitation "the concentrations" in Claims 1 & 7. There is insufficient antecedent basis for this limitation in these claims.

8. Claims 2 & 8 recite the limitation "the response determination" in Claim 1. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 4, 7, & 8 recite the limitation "the oxygen content" in any one of Claims 1 to 3, and Claim 7 respectively. There is insufficient antecedent basis for this limitation in these claims.

10. Claims 2-4, 7-10, & 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the Examiner how reciting a separate limitations to a separate component that is not part of the flow analysis or flow injection analysis system (reagent solution, auxiliary solution, & sealed vessels), further limits the structure of the flow analysis or flow injection analysis system.

11. Further, it is unclear how the limitations of the type of solution further limits the structure of the flow analysis or flow injection analysis system;

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12. Lastly, it is unclear how the method of using the flow analysis or flow injection analysis system (Claim 13) further limits the structure of the flow analysis or flow injection analysis system

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-4, 7-10, & 13 are rejected under 35 U.S.C. 102(b) as being anticipated by MORTON.

15. Applicants' claims are toward a system.

16. Regarding Claims 1-4, 7-10, & 13, MORTON discloses the flow analysis system or flow injection analysis system, capable of quantitatively or semi-quantitatively determining elements to be detected (See Figure 2 & See Abstract), contained in a sample solution, to which a sealed vessel is connected in which a reagent solution is encapsulated, said reagent solution generating a detectable response according to the concentrations of the elements to be detected, contained in the sample solution, wherein the sealed vessel in which the reagent solution is encapsulated is composed of a material having an oxygen permeability of $10 \text{ fmol/m}^2 \cdot \text{s} \cdot \text{Pa}$ ($2 \text{ cc/m}^2 \cdot \text{d} \cdot \text{atm}$) or less.

17. The Examiner interprets the sample solution, the sealed vessel containing the reagent solution as separate from the system (Claims 1 & 7); the vessel further

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connected to the system which contains the auxiliary solution (Claim 2), the auxiliary solution is at least one selected from a carrier solution, a neutralizing solution, an oxidizer solution, a buffer solution, a standard solution of the element to be detected and a blank solution (Claims 3 & 9); the oxygen content in the reagent solution or the auxiliary solution as encapsulated in the sealed vessel is 5 ppm or less (Claims 4 & 8) and; the sealed vessel in which the reagent solution or the auxiliary solution is encapsulated is composed of a material having an oxygen permeability of $10 \text{ fmol/m}^2 \cdot \text{s} \cdot \text{Pa}$ ($2 \text{ cc/m}^2 \cdot \text{d} \cdot \text{atm}$) or less (Claim 10) as limitations that are separate from the system. These limitations do not further limit the structure of the flow analysis system or the flow injection analysis system as claimed. In addition, Claim 13: A flow analysis system or flow injection analysis system, capable of quantitatively or semi-quantitatively determining elements to be detected, contained in a sample solution, on the basis of the difference between a first response with respect to a first solution flowing through a channel and a second response as a baseline value with respect to a second solution flowing through the channel, wherein the second solution flowing through the channel contains a response-suppressing substance which acts to suppress the response by the reagent solution, is a intended use; there is no structure which limits the flow analysis system or the flow injection analysis system. MORTON's flow analysis system meets the claim limitations.

18. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by KAWABE ET AL (JP 03-172760).

19. Applicants' claims are toward a system.

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20. Regarding Claims 1-4, 7-10 & 13, KAWABE ET AL discloses the flow analysis system or flow injection analysis system, capable of quantitatively or semi-quantitatively determining elements to be detected (See Title; a liquid chromatograph involves either a flow analysis system or an injection system which is capable of quantitatively or semi-quantitatively determining elements), contained in a sample solution, to which a sealed vessel is connected in which a reagent solution is encapsulated, said reagent solution generating a detectable response according to the concentrations of the elements to be detected, contained in the sample solution, wherein the sealed vessel in which the reagent solution is encapsulated is composed of a material having an oxygen permeability of $10 \text{ fmol/m}^2 \cdot \text{s} \cdot \text{Pa}$ ($2 \text{ cc/m}^2 \cdot \text{d} \cdot \text{atm}$) or less (See Drawing 1 Item 1)

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. Claims 2-4, 7-10, & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over KAWABE ET AL in view O'LEAR ET AL (US5252486).

24. Applicants' claims are toward a system.

25. Regarding Claims 2-4, KAWABE ET AL discloses the flow analysis system or flow injection analysis system according to Claim 1. KAWABE ET AL does not disclose to which further connected is a sealed vessel in which an auxiliary solution, other than the reagent solution, necessary for the response determination is encapsulated, wherein the sealed vessel in which the auxiliary solution is encapsulated is composed of a material having an oxygen permeability of 10 fmol/m².s. Pa (2 cc/m².d.atm) or less. O'LEAR ET AL discloses a flow analysis system or flow injection analysis system capable of quantitatively or semi-quantitatively determining elements to be detected (See Figure 1), contained in a sample solution. O'LEAR ET AL further discloses a sealed vessel which is connected in which a reagent solution is encapsulated, said reagent solution generating a detectable response according to the concentrations of the elements to be detected, contained in the sample solution (see Figure 1 Items 25 & 31; reagents). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify O'LEAR ET AL with the sealed vessels of KAWABE ET AL because O'LEAR ET AL discloses the critical need to eliminate additional oxygen from entering the system and interfering with the analysis of the colorimeter (See column 5 lines 44-49).

26. Additional Disclosures Included: Claim 3: The auxiliary solution is at least one selected from a carrier solution, a neutralizing solution, an oxidizer solution, a buffer

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solution, a standard solution of the element to be detected and a blank solution (See Figure 1 Items 7 & 9).

27. Regarding Claim 4, the combination of KAWABE ET AL and O'LEAR ET AL discloses the flow analysis system or flow injection analysis system according to any one of Claims 1 to 3, except wherein the oxygen content in the reagent solution or the auxiliary solution as encapsulated in the sealed vessel is 5 ppm or less. O'LEAR ET AL does however disclose minimizing the amount of excess oxygen that may be introduced into the system that can interfere with measurements by the colorimeter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to minimize the oxygen content in the reagent solution or the auxiliary solution as encapsulated in the sealed vessel is 5 ppm or less since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

28. Regarding Claims 7 & 8, the combination of KAWABE ET AL and O'LEAR ET AL disclose the flow analysis system or flow injection analysis system, capable of quantitatively or semi-quantitatively determining elements to be detected, contained in a sample solution, to which a sealed vessel is connected in which a reagent solution is encapsulated, said reagent solution generating a detectable response according to the concentrations of the elements to be detected, contained in the sample solution, wherein the oxygen content in the reagent solution as encapsulated in the sealed vessel or a sealed vessel in which an auxiliary solution, other than the reagent solution, necessary for the response determination is encapsulated, wherein the oxygen content

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in the reagent solution as encapsulated in the sealed vessel is 5 ppm or less. Both references disclose the importance of preventing additional oxygen or minimizing the oxygen content to 5 ppm or less (The Examiner interprets deaerated in KAWABE ET AL to be within the claimed range). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination so that the oxygen content is within the range of 5 ppm or less to prevent/minimize noise from interfering with the signal from the colorimeter.

29. Additional Disclosures Included: Claim 9: The flow analysis system or flow injection analysis system according to Claim 8, wherein the auxiliary solution is at least one selected from a carrier solution, a neutralizing solution, an oxidizer solution, a buffer solution, a standard solution of the element to be detected and a blank solution (See Figure 1 Items 1 & 2); and Claim 10: The flow analysis system or flow injection analysis system according to any one of Claims 7 to 9, wherein the sealed vessel in which the reagent solution or the auxiliary solution is encapsulated is composed of a material having an oxygen permeability of 10 fmol/m².s. Pa (2 cc/m².d.atm) or less (See KAWABE ET AL; Figure 1; Item 1); Claim 13: The flow analysis system or flow injection analysis system, capable of quantitatively or semi-quantitatively determining elements to be detected, contained in a sample solution. The combination does not explicitly state that the system is used on the basis of the difference Δ between a first response with respect to a first solution flowing through a channel and a second response as a baseline value with respect to a second solution flowing through the channel, wherein the second solution flowing through the channel contains a response-suppressing

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substance which acts to suppress the response by the reagent solution (See Column 11 lines 49-67; the system is capable of performing this method because the computer is capable of using information of a preceding step (i.e. - baseline info)).

Telephonic Inquiries

The Examiner would like to make of record the following reference: KIKYOTANI ET AL (US5208160). This reference was not applied in the above Office Action, but may be used as prior art in a future office action because it clearly discloses a flow injection analysis system which comprises reagent solutions and auxiliary solutions that contain carrier solutions, neutralizing solutions, oxidizer solutions, and buffer solutions which would essentially need to be stored in sealed vessels with the particular limitations of KAWABE ET AL and an oxygen content of 5 ppm or less, to prevent degradation and extend the life span of these reagents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797